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Regulatory Affairs
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November 13, 2008

REGISTERED MAIL
RETURN RECEIPT REQUESTED

Environmental Protection Agency
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Company Sanitized

Attention: Document Control Officer

Dear Sir or Madam:

EPA Case number P-08-508 and P-08-509;
DuPont PMN TS-D1297P

On behalf of E. I. du Pont de Nemours and Company, I am pleased to submit the following revised pages of Attachment 103 and Page 28 of Attachment 3, in support of the Premanufacturing Notice identified by the DuPont number TS-D1372P and EPA Case numbers P-08-508 and P-08-509.

Attachment	Revised Pages
103	1054, 1056, 1057, 1058, 1060, 1061, 1063, 1074

If there are any questions, please call me at (302) 999-4018.

Very truly yours,

Donna C. Laudisi

Donna C. Laudisi
DuPont Regulatory Affairs
FluoroPolymer Solutions

Encs

P08-508|9 Amend

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Part III – LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.
Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confi-dential
94) Acute Eye Irritation in Rabbits - 4(B)	857-875	☐
95) Acute Dermal irritation Study in Rabbits - 4(B)	876-895	☐
96) Acute Oral Toxicity in Mice - Up-and-Down Procedure - 4(B)	896-926	☐
97) Determination of a Permeability Coefficient (Kp) for H-28308 Using Human and Rat Skin - 4(B)	927-931	☐
98) Acute Oral Toxicity Study in Rats - Up-and-Down Procedure – 4(A)	932-983	☐
99) [APFO during transition period]	984	☒
100) Acute Oral Toxicity Study in Rats Upand-Down Procedure - 4(B)	985-1020	☐
101) Reasonable Worse Case Scenario	1021	☐
102) Assessment of Ready Biodegradability By The CO2 Evolution Test - 4(B)	1022-1053	☐
103) Activated Sludge Respiration Inhibition Test - 4(B)	1054-1078	☐
104) Physical/Chemical Properties Worksheet for 4(A)	1079	☐
105) Physical/Chemical Properties Worksheet for 4(B)	1080	☐
106) Physical and Chemical Characteristics Summary	1081-1101	☐
107)Physical and Chemical Characteristics 4 (A)	1102-1115	☐
108)Physical and Chemical Characteristics 4 (B)	1116-1129	☐
109) Determination of the Dissociation Constant 4(B)	1130-1155	☐
110)Determination of Water Solubility and Vapor Pressure 4 (A)	1156-1199	☐
111) Determination of Water Solubility and Vapor Pressure 4 (B)	1200-1246	☐
112) An Assessment of Hydrolysis as a Function of pH - 4(B)	1247-1292	☐
113) Dispersions - Markets & Uses	1293-1299	☐
114) Customer Processing Conditions	1300-1315	☐
115) Study of Photochemical Properties Freon® E-1, Estimation of Atmospheric Lifetime & GWP	1316-1330	☐
116) In Vitro evaluation for Chromosome Aberations in Human Lymphocytes - Transformation Byproduct	1331-1353	☐
117) Mutagenicity Testing in the Samlmonella Typhimurium Plate Incorporation Assay - Transformation Byproduct	1354-1368	☐

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.

Study Title

[ ] ACTIVATED SLUDGE RESPIRATION INHIBITION TEST (OECD 209)

Test Guideline

OECD (1984) Guideline for Testing of Chemicals, Section 2, No. 209: "Activated Sludge, Respiration Inhibition Test", adopted April 4, 1984

Authors

[ ]

Study Completion Date

05-September-2008

Revision No. 1 Completion Date

21-October-2008

Test Facility

DuPont Haskell Global Centers for Health & Environmental Sciences
Central Research & Development
Glasgow, Building 300, P.O. Box 6300
Newark, DE 19714-6300

Submitter

[ ]
E. I. du Pont de Nemours and Company
Wilmington, Delaware 19898
U.S.A.

Work Request/Service Code

[ ]

DuPont Report Number

[ ]

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

The study described in this report, with the exception of the items listed below was conducted in compliance with the following GLP Standards:

United States Environmental Protection Agency, (TSCA), Title 40 Code of Federal Regulations Part 792

which are consistent with:

The OECD Principles on Good Laboratory Practice (as revised 1997), ENV/MC/CHEM98(17), OECD, Paris, 1998

MAFF Japan Good Laboratory Practice Standards (11 Nousan Number 6283).

The following items are exceptions to the GLP Standards. These items do not impact the validity of the study.

The reference substance was not characterized under GLP. The test substance was provided by the sponsor. The reference substance is a commercially available material provided by a commercial supplier. The Certificates of Analysis were provided by the sponsor and supplier and the accuracy of the data is considered sufficient for the purposes of this study.

Study Director

[ ]

Sponsor/Submitter

Date

QUALITY ASSURANCE STATEMENT

Study Number

[ ]

Study Title

[:] Activated Sludge Resiration Inhibition Test (OECD 209).

The conduct of this study was subjected to periodic Quality Assurance inspections. The dates of inspection are indicated below:

Study Phase Inspected	Inspection/Audit Dates	Dates Findings Reported to Study Director	Dates Findings Reported to Management
Protocol	15-April-2008	15-April-2008	21-April-2008
Study setup up and dosing	24-April-2008	16-June-2008	16-June-2008
Study records and final report	04-August-2008	08-August-2008	05-Sept.-2008
Report Revison No. 1	16-October-2008	16-October-2008	16-October-2008

[ ]

21 Oct. 2008
Date

CERTIFICATION OF AUTHENTICITY

[ ] ASSESSMENT OF BIODEGRADABILITY BY THE ACTIVATED SLUDGE RESPIRATION INHIBITION TEST (OECD 209)

We, the undersigned, declare that the work described in this report was performed under our supervision, and that this report provides an accurate record of the procedures and results.

Report by:

[ ]

21-Oct-2008
Date

21-Oct-2008
Date

Approved by:

[ ]

21-Oct-08
Date

Study Initiation Date:
23-April-2008

Date Study Completed:
05-September-2008

Revision No. 1 Completion Date:
21-October-2008

Submitter:

[ ]
DuPont Co.
Wilmington, Delaware 19880 U.S.A.

[ ]: ACTIVATED SLUDGE RESPIRATION INHIBITION TEST (OECD 209)

Authors

[.]

0.0 REASONS FOR REVISION

- The WR number appearing on the title page was corrected.
- The notebook number appearing on the first page was moved to page 8.

1.0 SUMMARY

Test System:

[ ] was tested for toxicity towards activated sludge according to OECD Guideline 209 in the version dated 4-April-1984. For the determination of the toxic behavior of the test substance, activated sludge from the aeration tank of a municipal sewage treatment plant was exposed to the test substance at 10, 32, 100, 320, and 1000 mg L^{-1} nominal concentrations. For the reference substance 3,5-dichlorophenol, activated sludge was exposed at 3.2, 10, and 32 mg L^{-1} nominal concentrations. After a three hour incubation period, the inhibition of the respiration rate of the activated sludge was determined in comparison to a test solution without any test or reference substance.

Findings:

Under the conditions of the test, there was no significant activated sludge respiration inhibition (inhibition less than 15%) at concentrations of the test substance [ ] as high as 1000 mg L^{-1} (1000 ppm) compared to the positive controls to which the test substance was not added.

The Effective Concentration of the reference substance 3-5, dichlorophenol at which 50% inhibition occurred (EC_{50}) was approximately 10 mg L^{-1}.

The difference between the respiration rates of the two positive controls measured at the start and end of the test was less than 10%.

Conclusions:

The Effective Concentrations of the test substance at which 20, 50, and 80% inhibition occurred (EC_{20}, EC_{50}, EC_{80}, respectively) could not be determined because there was no inhibition at the highest test concentration of 1000 mg L^{-1}.

The test is valid.

2.0 GENERAL STUDY INFORMATION

Study Objectives

The aim of this study was the determination of the acute toxic behaviour of [ ] towards the microorganisms of activated sludge according to OECD guideline 209 in the version of April 4, 1984. The objectives of this study were to determine the:

- Effect of the test substance,[ ], on microorganisms from municipal sewage sludge, using a microbial inoculum and a artificial sewage feed and measuring the respiration rate of the test system after a three (3) hour time period under controlled laboratory conditions.
- Suitable non-inhibitory concentrations of the test substance to be used in biodegradability tests

Test System Justification

The test system is outlined by the OECD guideline 209 and was requested by the submitter.

Study Personnel

Management:	[.]
Study Director:	[ ] DuPont Haskell Global Centers for Health & Environmental Sciences Central Research & Development, Glasgow Building 300 PO Box 6300 Newark, DE 19714-6101 USA
Technical Personnel:	[ ] [ ]
Notebook Number	[ ]

Study Execution Dates

Experimental Start Date:	24-April-2008
Experimental Completion Date:	08-May-2008
Study Completion Date:	05-September-2008
Revision No. 1 Completion Date	21-October-2008

3.2.1.3 Test Vehicle

The test substance was dissolved in a stock solution of Barnstead Diamond™ water at 10,000 mg L^{-1}. The concentration of the test substance in the stock solution was determined to be 9370 mg [ ] L^{-1}.

3.2.1.4 Application Information

The test substance was added to the test vessels at the following nominal concentrations: 1000, 320, 100, 32 and 10 mg L^{-1}.

3.2.2 Biological System

Secondary activated sludge from Wilmington, DE USA Publically Owned Treatment Works (POTW) was used as the microbial inoculum. The activated sludge was kept aerated and fed with synthetic sewage feed. The amount of sludge to use as inoculum is determined by measuring its respiration rate at 50, 100, and 200 mL of sludge after diluting with 16 mL of synthetic sewage feed and sufficient dechlorinated water for a final volume of 500mL. The respiration rate will be measured after a minimum mixing time of 30 minutes. This pre-experiment to determine the amount of sludge to use as inoculum will not be performed in compliance with the GLP-Regulations. The raw data, however, will be included in the study records and will be archived under the project number of the study.

3.2.3 Physical System

3.2.3.1 Test Units

All test vessels are 1000 mL glass flasks and contain a final volume of 500 mL. Test solutions were transferred to 300-mL Biological Oxygen Demand (BOD) glass bottles for Dissolved Oxygen (DO) determinations.

3.2.3.2 Test Conditions

Test solutions were aerated with compressed air at a flow rate of approximately 0.1 to 0.5 liter per minute at room temperature.

3.3 Test Conduct

Prior to the start of the test, all components were added to the test vessels, less the volume of the inoculum. This volume is determined by a pre-test of the inoculum to find a concentration that gives an acceptable respiration rate. The test was initiated with the first positive control by adding the microbial inoculum and aeration started. After approximately 15 minutes the inoculum was added to the first reference substance. The procedure was repeated at approximately 15-minute intervals with the reference substance and then the test substance to give a series of vessels containing different concentrations of the reference and test substance. A negative control (synthetic sewage feed and test substance at the highest concentration, but without microbial inoculum) test was also evaluated. The final flask was a second positive control, prepared exactly as the first.

Reference substance 32:
32 mg/L 3,5-dichlorophenol

Reading Number	Time	DO Reading
	sec	*mg/L*
1	0	7.04
2	30	6.98
3	60	6.95
4	90	6.91
5	120	6.89
6	150	6.85
7	180	6.80
8	210	6.77
9	240	6.73
10	270	6.69
11	300	6.67
12	330	6.63
13	360	6.6
14	390	6.56
15	420	6.52
16	450	6.48
17	480	6.45
18	510	6.38
19	540	6.35

Reference substance 10:
10 mg/L 3,5-dichlorophenol

Reading Number	Time	DO Reading
	sec	*mg/L*
1	0	6.53
2	30	6.35
3	60	6.25
4	90	6.17
5	120	6.06
6	150	5.97
7	180	5.88
8	210	5.78
9	240	5.69
10	270	5.59
11	300	5.51
12	330	5.42
13	360	5.33
14	390	5.23
15	420	5.15
16	450	5.06
17	480	4.96
18	510	4.87
19	540	4.78
20	570	4.69